



November 6, 2003

Food and Drug Administration  
Rockville MD 20857

Ram Kamath  
Scott McKibbin  
Special Advocates for Prescription Drugs  
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Chicago, Illinois 60601

Dear Dr. Kamath and Mr. McKibbin:

I write to respond to the report that you presented last week to Governor Blagojevich on the feasibility of purchasing prescription drugs from Canada. Let me say at the outset that we here at the Food and Drug Administration fully understand and appreciate the concerns Governor Blagojevich has about the need for assisting Illinois citizens who cannot afford their prescription medications, and the need for addressing the rising prescription drug costs being borne by state and local governments. Public officials across the country, at all levels of government, are struggling to find answers to these problems. We believe that further actions are needed to reduce prescription drug costs without creating new safety risks for patients, especially at a time when the potential threats to drug safety from counterfeit drugs, unapproved drugs, and drugs that are improperly dispensed and used are greater than ever.

As FDA Commissioner Mark McClellan has repeatedly stated, Americans deserve access to drugs that are safe, effective and affordable. And the FDA is doing something about it. Earlier this year, we accelerated the process that brings generic drugs on the market, reducing overall health care costs over the next ten years by an estimated \$35 billion. In addition, the agency is advancing several programs to lower the costs of both drug development and manufacture, and to help prevent costly medical errors and drug-associated complications. And, of course, the Administration and Congress are closer than ever to enacting a prescription drug benefit as part of Medicare that will substantially increase access to affordable prescription drugs for seniors.

In 1987, in response to instances of unapproved and unsafe foreign medicines entering the United States, Congress enacted legislation to prohibit the importation of unapproved medicines. While the public health threats caused by such medications were significant enough for Congress to act in 1987, the potential threats from unapproved prescription drugs are even greater today. Unapproved and unregulated medicines bought over the Internet can come from *anywhere*. Even medicines that appear to be the same or have the same brand name as those bought in the United States can be dangerously different. We cannot and must not allow the Internet to become the 21<sup>st</sup> Century's snake oil outlet.

Unregulated importation endangers the lives of America's seniors. Recently an 82-year old man suffering from epilepsy and an enlarged prostate purchased what he was led to

believe were FDA-approved drugs from a web site purportedly representing a Canadian pharmacy. Upon receipt, he noticed that they were from India. He called the FDA, and we determined that not only were the drugs not from Canada, but were, indeed, fake “knockoffs” of an American drug. “Buyer Beware” is bad health care practice and even worse health care policy.

In considering any proposal that affects the health of the public, it is important to consider the risks and benefits. On the “benefit” side, your report is misinterpreted to mean that importing drugs from Canada would be a smart bargain for Illinois employees and retirees, when this is far from the truth. Your estimate of maximum possible savings of more than 27 percent of drug spending greatly overstates the net savings the plan might achieve in practice. Indeed, this estimate appears to represent an implausible upper-boundary that inappropriately assumes “all eligible prescriptions are filled through the proposed Canadian Mail Order Plan.” In fact the report states “Based on current domestic mail order participation of approximately 7 percent of eligible prescriptions, we would estimate a participation rate of at least 33 percent given the extremely small proposed out-of-pocket cost to the participant.” Thus the best guess of savings would be about 9 percent annually. And most of these hypothetical, limited savings would be for the government. According to your report’s own estimates, patients would receive only about a third of the savings. Even these small estimated savings substantially overstate the likely effect because important costs – pharmacist costs, shipping costs, liability costs, and others – are omitted.

Against these relatively modest savings are important health risks that are either misunderstood or ignored in your report. These risks indicate that there are far better ways to get savings in medical costs for Illinois residents than by turning to a questionable importation scheme.

On the “risk” side, the report fails to address the implications of buying drugs through the regulatory gap that exists at the border. Your report wrongly assumes regulatory oversight by Canadian health authorities of drugs exported to our citizens, when those authorities have not been willing or able to guarantee the safety of drugs sold to Americans. We understand that you did not include Health Canada in your fact-finding trip to Canada, nor otherwise sought assurances from Canadian health authorities that they would assure that drugs imported to Americans meet FDA’s standards for drug quality, safety and purity. Your report also assumes the safety of drugs that happen to be imported across the U.S.-Canadian border. While we have often noted that Canadian health authorities set high standards for drugs sold to their citizens, we have also consistently observed that drugs sold outside of the U.S. and Canadian systems (e.g., over the Internet) often do not meet such high standards. Indeed, we have seen concrete examples of drugs sold to Americans by Canadian Internet pharmacies that pose a risk to our citizens.<sup>1</sup>

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<sup>1</sup> Just recently, FDA surveyed drugs being imported through four mail facilities, which revealed serious safety concerns about a number of Canadian imports. For example, FDA found that taro-warfarin, an apparently unapproved version of warfarin, was being shipped to U.S. patients. FDA-approved warfarin is used to prevent blood clotting, and its potency may vary depending on how it is manufactured. Life-

We are also concerned that your plan, if implemented, would be in direct conflict with Federal and state law. As you know, prescription drugs sold in the United States must be approved by the FDA before they can enter the market, and drugs from foreign countries would generally not meet that requirement. I would leave it up to your pharmacy and legal experts to judge whether the program would violate current Illinois state pharmacy law, which parallels the Federal law, and also requires that drugs dispensed in Illinois be dispensed only by state-licensed pharmacies.

Drugs imported from Canada virtually never have the FDA-approved U.S. labeling, which is designed to inform patients about the drug's proper use and to give them warnings about particular dangers inherent in the drug. As a result, it is unclear how under this plan Illinois would ensure that its citizens get the necessary information and warnings.

Liability is another critical issue that the report fails adequately to address. It is inconceivable to FDA scientists that there will not be some injuries arising from the sale of unapproved drugs to your employees or citizens. Selling such unregulated products will require substantially more liability insurance than is currently the case, unless Illinois consumers bear the risk of such injuries themselves. The costs of the additional insurance premiums are excluded from the cost estimates presented in the report. Given that wrongful death settlements are commonly millions of dollars, it is quite plausible that the net savings from the Illinois proposal, measured properly to net out the increased liability cost, would be significantly smaller than the 9 percent estimate mentioned earlier. Moreover, we query whether the state would be potentially liable in tort if a drug that the state purchased and sold in violation of Federal law injured an Illinois citizen. FDA has not researched and does not advise you of any tort liability that will necessarily arise, but we urge that state officials consult with the appropriate legal advisors, as it is clear that the drugs purchased will be illegal and that safety concerns about them were discussed in our recent meeting with you. Finally, purchases of drugs from Canada will presumably be made over a disclaimer to the effect that the international "pharmacy" does not assure the safety of its products; such disclaimers are common among Canadian Internet pharmacies. The history of drug regulation and legislation in the U.S. suggests it is detrimental to the health of Illinois citizens to be expected to obtain their medical care under such "buyer beware" conditions, but the report neglects the costs of making some other party liable. It does not appear that Illinois has or is developing any mechanism in place to evaluate adverse events occurring in their employees and retirees who use imported drugs.

Your program assumes that pharmacists in Illinois will participate in your primary care pharmacist model. Although pharmacy practices have become much more efficient in recent years, we are skeptical that pharmacists will participate in the plan unless they are adequately compensated both for "primary care" services and for the liability risks

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threatening bleeding may result if the patient doesn't get the proper drug with proper monitoring during treatment. The taro-warfarin being sent from Canada was apparently not the FDA-approved version and could thus potentially pose serious safety risks. Other similar examples were found in the surveys.

associated with providing unapproved drugs. Defraying these costs could easily consume all of the savings your plan claims that it will generate, and it might even cost more.

We also wish to point out that, in some areas, your report suggests limited knowledge of how pharmaceutical distribution practices actually work. This has implications for safety as well. For example, your plan states that drugs exported from Canadian pharmacies are shipped in “unit-of-use” containers that would reduce both medication errors and the likelihood of counterfeit drugs—because pills are packaged as individual units in tamper-resistant packaging. However, our surveys of the actual drugs being mailed to Americans patients from Canada have found that very few are in true “unit-of-use” containers. Rather, the drugs tend to be more in the manufacturers’ “stock” bottles, which tend to come in specific large volume amounts (e.g., 100 tablets).<sup>2</sup> These bottles are not intended to be used by individual patients whose prescriptions are for more or less than 100 units; moreover, they do not generally include appropriate labeling and warnings for patients. Thus, medication errors can actually be encouraged, and many patients appear to be getting larger quantities than their doctors are prescribing. Further, although you are correct that true unit-of-use packages may help deter counterfeiters, such criminals have proven to be quite adept at accurately copying manufacturer stock bottles.

You also claim in your report that counterfeiting of drugs is less likely to occur in Canada than in the United States. But it is incorrect to imply that counterfeiting is not a real threat across the border. In fact, we have a number of counterfeiting cases under investigation with our colleagues at the Royal Canadian Mounted Police. Moreover, an importation plan such as this, with no reliable anti-counterfeiting measures included and with some fundamental misunderstandings of how drugs are distributed in Canada, could encourage counterfeiters to increasingly use Canada as an entry point for the U.S. market.

I would like to encourage your task force to consider a broader range of options for reducing the costs of safe and effective drugs. For example, although generic drugs comprise more than half of prescriptions filled in the U.S. today, many Americans do not realize that generic versions of brand name drugs are available and are much less expensive for treating their health problems. Generics in the U.S. are also generally cheaper—often much cheaper—than generic drugs in Canada. Many of the drugs on your approved list either have generic versions available or involve conditions for which much less expensive generic versions are available. So I urge you to consider proven and safe sources of savings as you develop whatever program emerges for your citizens. And, as you may know, at the FDA we have taken many steps to speed the availability of more generic drugs, leading to billions of dollars in savings for patients, as well as to help doctors and patients get better information on the treatments available to meet their medical needs. And as soon as Congress acts, the purchasing power of a Medicare drug benefit will allow seniors who get little assistance with drug costs today to access drugs at much lower prices. And there are steps you can take as well. For example, well over

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<sup>2</sup> Our colleagues at the Consumer Product Safety Commission, which oversees the child resistant packaging laws to protect children from accidental drug poisoning, inform us that these “stock bottles” that are so commonly sent to U.S. citizens also violate those safe drug packaging statutes, and, as such, will place our children at increased risk.

ten percent of the drugs on your list have generic or therapeutic equivalents versions available in the United States, which are just as safe and effective as brand name drugs but generally cost about 70 percent less, and are less expensive in the United States than in Canada. Encouraging the use of such drugs widely could achieve substantial savings, without compromising safety or quality at all.

We would add that there are other flaws in the report that suggest that even savings of 9 percent are significantly higher than what the plan will realize.

- Even the 33 percent participation rate that you preferred in the report may be too high because Canadian purchases would be limited to repeat prescriptions, and would require a detailed medical history for the patient. Some patients may elect not to participate because the twelve-dollar shipping costs may be higher than the patient's co-pay in some insurance plans.
- The estimated cost savings appear not to net out that \$12 per shipment delivery cost. Correctly accounting for shipping costs would significantly lower the estimate of total cost savings.
- The report underestimates program implementation costs by about \$2 million through an inadvertent math error.
- The report overstates cost savings by inappropriately comparing current spending on drugs by the State of Illinois, with spending on large packages intended to provide a long-term supply of drugs. This analytic approach artificially overstates savings because these larger packages are typically cheaper on a per day basis. The report also wrongly neglects the additional inconvenience and financial risk to consumers of buying drugs in 90 day supplies and then being unable to return them for cash or credit to mail order Canadian-based pharmacists if their prescriptions are changed for medical reasons.

In conclusion, I want to repeat that we agree with Governor Blagojevich that we must find better ways of ensuring access to affordable drugs for all Americans. But we must not compromise safety in the process. Your proposal for "buyer beware" drugs simply doesn't achieve the key goals of affordability and safety. Importing unregulated foreign drugs will not accomplish those dual goals.

Compromising safety for price is not in the best interest of the American public, and we should not force Americans to settle for that. We at the FDA are working diligently to help find solutions that do not force Americans to choose between medicines that are safe, and medicines that are affordable. Finally, the U.S. public health system should not be undermined by schemes that put those most in need most directly at risk.

Sincerely,



William K. Hubbard  
Associate Commissioner for Policy & Planning